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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.       |
|---|-------------|----------------------|---------------------------------|------------------------|
| 10/655,571  | 09/04/2003  | John A. Sazy         | 101896-706<br>(DEP-128CON)      | 6429                   |
| 21125 7590 06/01/2007<br>NUTTER MCCLENNEN & FISH LLP<br>WORLD TRADE CENTER WEST<br>155 SEAPORT BOULEVARD<br>BOSTON, MA 02210-2604 |             |                      | EXAMINER<br>PELLEGRINO, BRIAN E |                        |
|   |             |                      | ART UNIT<br>3738                | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>06/01/2007         | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/655,571

Applicant(s)

SAZY, JOHN A.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 10-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 10-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/4/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/16/07 has been entered.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the body having a first radius of curvature equal to the second radius of curvature must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

Art Unit: 3738

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11,12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "the quadrilaterals" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the parallelograms" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 3738

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3-6,13,14,19,28,30 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Schafer et al. (6143032). Fig. 3 shows a unitary body that is banana-shaped as viewed from above. Fig.2 illustrates the body has openings evenly spaced about the circumference. Schafer discloses the body has a continuous front arc and a continuous back arc with two radiuses of curvature either equal or different, col. 2, lines 26-32. Schafer also discloses the implant body can be made of a metal or polymer, col. 3, lines 14,15. According to Figs. 1 and 3, it can be construed that the width is greater than the length. Regarding Claim 30 is also rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Schafer et al. It would have been an obvious matter of design choice to modify the ratio of length to width, since applicant has not disclosed that using a width at least 2.4 times greater the length provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the dimensions taught by Schafer or the claimed 2.4 times width in claim(s) 30 because both spinal implants perform the same function of supporting vertebrae.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Harms et al. '305. Schafer et al. is explained supra. However, Schafer fails to teach the openings are parallelograms or rhombuses. Harms et al. show (Fig. 4) rhombus or parallelogram shaped openings (col. 2, lines 15,16) which allow bone cement to be placed through the openings. It would have been obvious to one of ordinary skill in the art to modify the shape of the openings and use parallelograms or rhombuses as taught by Harms with the implant of Schafer such that they provide a greater surface area to bond to.

Claims 15-18,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Dove et al. '261. Schafer et al. is explained supra. However, Schafer et al. fail to disclose the types of metals or polymers for the prosthesis is made from a carbon-fiber reinforced plastic or a resorbable polymer or stainless steel. Dove et al. teach that the spinal implant can be made from a variety of materials, such as carbon fiber reinforced polymers or stainless steel or biodegradable material, col. 1, lines 46-51. It would have been obvious to one of ordinary skill in the art to use alternative materials as taught by Dove et al. for the implant of Schafer et al. such that it can provide a lighter implant or a more radiopaque implant or one that degrades as tissue ingrowth occurs.

Claims 24,25,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Michelson (6302914). Schafer et al. is explained above. However, Schafer et al. fail to disclose the implant's width or length. Michelson (Fig. 18) shows a spinal cage for supporting the vertebrae. Michelson also teaches that the

Art Unit: 3738

height and width of the implant correspond to the area that a disc may have been removed, col. 7, lines 47-56. It would have been obvious to one of ordinary skill in the art to use an implant with a width falling within the range of 24-28mm and a length of about 10mm as taught by Michelson for the implant of Schafer et al. such that it can provide the proper dimensions of the patients intervertebral space and support adjacent vertebrae.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Dove et al. '261 as applied to claim 20 above, and further in view of MacMillan et al. (5062850). Schafer et al. in view of Dove et al. is explained supra. However, Schafer as modified by Dove fail to disclose the use of polyglycolic acid for the spinal support device. MacMillan et al. teach the use of polyglycolic acid for the vertebral prosthesis because it slowly degrades, col. 6, lines 5-10. It would have been obvious to one of ordinary skill in the art to use polyglycolic acid as the implant material as taught by MacMillan et al. for the vertebral implant of Schafer et al. as modified by Dove et al. such that it degrades slowly to provide space for bone ingrowth.

Claims 22,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Preissman (6231615). Schafer et al. is explained supra. However, Schafer fails to disclose the use of an antibiotic with the polymer or plastic. Preissman teaches the use of injectable PMMA and the use of an antibiotic, col. 4, lines 2-10. Preissman also teaches the injectable PMMA is used in treating pain in vertebral compression fractures, col. 3, lines 65-67. It would have been obvious to one of ordinary skill in the art to inject polymethylmethacrylate with an antibiotic as taught by

Art Unit: 3738

Preissman with the vertebral implant of Schafer et al. such that it enhances the treatment given to the patient to reduce infection and provides an efficient way to deliver a cement to aid in fixation and an antibiotic to the treatment site.

Claims 26,27,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of McKay '449. Schafer et al. is explained supra. However, Schafer fails to teach the height to be about 10mm or the thickness of front arc of the implant to be about 1.5-2mm or the upper and lower edges of the implant formed with smoothly-sloping surfaces in a serpentine arrangement. McKay teaches (Fig. 3) a mesh type implant with the upper and lower surfaces having smoothly-sloping serpentine structure for engagement with the vertebrae. McKay additionally teaches that the serpentine upper and lower edges are for attaching or affixing to the vertebrae, col. 6, lines 24,25. McKay teaches (Fig. 5) a spinal implant and that the thickness of a front arc can be "about 1mm". McKay also teaches (col. 6, lines 38-40, 53,54) the thickness is sufficient to support the vertebrae and not break. The Examiner is interpreting "about 1.5mm" to be "about 1mm". It would have been obvious to one of ordinary skill in the art to use a thickness for the arc of the implant of "about 1.5mm" as taught by McKay for the implant of Schafer such that it provides a durable support for the vertebrae that can withstand compressible loads. McKay also teaches the height of the implant to be 10mm, col. 6, line 36. It would have been obvious to one of ordinary skill in the art to use the teaching of providing a spinal cage with a height of 10mm as taught by McKay for the implant of Schafer such that it provides enough space between the vertebrae and approximates the natural disc space, col. 2, lines 62,63 of McKay. The use of a



Art Unit: 3738

serpentine arrangement for affixing the implant to the vertebrae is well known in the art and would have been obvious to one of ordinary skill to incorporate the smoothly-sloping serpentine arrangement as taught by McKay with the cage of Schafer such that the implant does not move between the vertebrae once implanted.

### ***Response to Arguments***

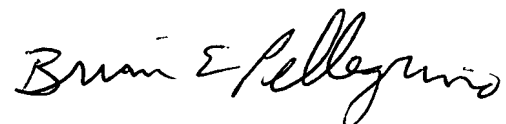
Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Friday from 8:30am to 5pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738



**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**